

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		Form Approved: OMB No. 0910-0387 Expiration Date: December 31, 2001.	
INITIAL REGISTRATION OF DEVICE ESTABLISHMENT (Shaded Areas are for FDA Use Only)		VALIDATION	
RETURN THIS FORM TO: Food and Drug Administration, Center for Devices and Radiological Health, (HFZ-308), 9200 Corporate Blvd., Rockville, MD 20850-4015		1. REGISTRATION NO.	
Public reporting burden for this collection of information is estimated to average .25 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Food and Drug Administration Center for Devices and Radiological Health (HFZ-308) 9200 Corporate Blvd. Rockville, MD 20850-4015 An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.			
NOTE: This form is authorized by Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act(21 U.S.C.331(p)). Persons who violate this provision may, if convicted, be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(q)(2) and may be a violation of 18 U.S.C. 1001.			
SECTION A			
2. ESTABLISHMENT BUSINESS NAME		3. RECORD DATE (Mo.) (Day) (Year)	
4. NUMBER AND STREET	5. CITY AND FOREIGN STATE	6. STATE	7. ZIP CODE
8. FOREIGN COUNTRY	9. ESTABLISHMENT TYPE (See Instruction Booklet) C DD E M R S T U X ID		10. PREPRODUCTION N <input type="checkbox"/> YES <input type="checkbox"/> NO
SECTION B			
11. OWNER/OPERATOR BUSINESS NAME		12. OWNER/OPERATOR I.D.	
13. NUMBER AND STREET	14. CITY AND FOREIGN STATE	15. STATE	16. ZIP CODE
17. FOREIGN COUNTRY	18. TELEPHONE NUMBER--IF DIFFERENT FROM THAT OF OFFICIAL CORRESPONDENT		
SECTION C			
19. OFFICIAL CORRESPONDENT/U.S. DESIGNATED AGENT		20. REGISTRATION NUMBER	
21. BUSINESS NAME			
22. NUMBER AND STREET	23. CITY	24. STATE	25. ZIP CODE
26. TELEPHONE NUMBER (Area Code)		27. FAX NUMBER (Area Code) (Number)	
SECTION D			
28. OTHER BUSINESS TRADING NAMES (Enter any other name which the establishment in field #2 uses. Do not list Registered trademarks or names of private label distributors. This is usually any name such as a brand name which is not the firm name.)			
SEQ	BUSINESS NAME	SEQ	BUSINESS NAME
SO1		SO4	
SO2		SO5	
SO3		SO6	
SECTION E			
29. SIGNATURE OF OFFICIAL CORRESPONDENT		30. TITLE	